PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors:	Raymond P. Johnston et al.	**Examiner:**	Ardin H. Marschel
App. No.:	09/612,418	**Group Art Unit:**	1631
Filing Date:	July 7, 2000		
Title:	DETECTION ARTICLE HAVING FLUID CONTROL FILM	**Docket No.:**	54971US006 (27987-228356)

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

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Theresa Belland

TRANSMITTAL LETTER

Enclosed for filing are the following papers in connection with the above-identified patent application:

1. Appeal Brief (submitted in triplicate);
   a. Appeal Brief Fee ($500);
2. Credit Card Authorization Form in the amount of $500; and
3. Return Receipt Postcard.

In the event the amount submitted herewith is insufficient in any respect, the Commissioner is hereby authorized to charge the balance needed to our Deposit Account No. 06-0029 and notify us of the same.

Respectfully Submitted,

RAYMOND P. JOHNSTON et al.

Dated: February 2, 2005

By: Paul Busse

Paul W. Busse, #32,403
FAEGRE & BENSON LLP
2200 Wells Fargo Center
90 South Seventh Street
Minneapolis, MN 55402-3901
(612)766-7046

M2:20689254.01

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Theresa Belland

APPEAL BRIEF

The Applicants filed a Notice of Appeal in this application on December 8, 2004 from the final rejection of the Examiner dated June 8, 2004.

This Appeal is proper because the present application includes claims that have been finally rejected. Applicants' Brief in support of this Appeal follows.

REAL PARTY IN INTEREST

The real party in interest in this Appeal is 3M Innovative Properties Company. An assignment of the inventors' rights to 3M Innovative Properties Company was recorded in the United States Patent and Trademark Office on March 6, 2001 at Reel 11670, Frame 610/12.

RELATED APPEALS AND INTERFERENCES

There are no known appeals or interferences related to this Appeal.

STATUS OF CLAIMS

The present application was originally filed with 101 claims. In an Office Action dated September 11, 2001, the Examiner restricted the claims into two Groups. Group I included claims 1-95 and Group II included claims 96-101. In the event the Applicants were to elect

Group I, the Examiner also required an election from a number of species. In a response dated October 10, 2001, the Applicants elected Group I and elected species F, including independent claim 1 and dependent claims 2-9, 13, 39-41, 43-46, 49, 50, 53, 54, 60, 61, 72-75, 77 and 81-85.

In a first Office Action on the merits, dated July 16, 2002, the Examiner withdrew the non-elected claims and rejected the remaining claims. Claims 1-9, 13, 39-41, 43-46, 49, 50, 53, 54, 60, 61, 72-75, 77, and 81-85 were rejected under 35. U.S.C. § 112, second paragraph, as indefinite. In addition, claims 1-7, 13, 39-41, 43-46, 53, 54, 60, 61, 72-75, 77, and 81-85 were rejected under 35 U.S.C. § 102(b) and (e) as being anticipated by each of U.S. Patent Nos. 4,469,601 (Beaver et al.), 4,810,381 (Haven et al.), and 5,451,504 (Fitzpatrick et al.). A response was filed by the Applicants on October 9, 2002. On February 18, 2003, claims 1-7, 13, 39-41, 43-46, 53, 54, 60, 61, 72-75, 77, and 81-85 were finally rejected as anticipated in view of the same references. Claims 8, 9, 49, and 50 were objected to as being dependent upon a rejected claim. After a response on May 9, 2003, another office action (non-final) was issued on August 18, 2003. The anticipatory rejections relying on the previously cited references were withdrawn. However, all of the claims were rejected as indefinite. Moreover, all of the claims were rejected as anticipated in view of two new references. Claims 1-3, 5-7, 13, 39-41, 43-46, 53, 54, 60, 61, 72-75, 81, and 83-85 were rejected as anticipated by U.S. Patent No. 6,416,642 to Marja Liisa Alajoki ("Alajoki"). Claims 1-7, 39-41, 43-46, 49, 50, 53, 54, 60, 61, 72-75, 81, and 83-85 were rejected as anticipated by U.S. Patent No. 4,673,657 to Clifford N. Christian ("Christian"). After another response on October 31, 2003 (filed again as a supplemental response on January 21, 2004), all of the claims were rejected on April 7, 2004 as containing new matter. The rejections based on Alajoki and Christian were also renewed. A final response was filed on September 8, 2004 and, after an Advisory Action on December 7, 2004, a Notice of Appeal was filed on December 8, 2004.

Accordingly, claims 1-9, 13, 39-41, 43-46, 49, 50, 53, 54, 60, 61, 72-75, 77, and 81-85 are the subject of this Appeal. A set of the claims as pending is set forth in the Appendix attached hereto.

STATUS OF AMENDMENTS

A response was presented on September 8, 2004 after the final office action containing only arguments and no amendments. The final amendments to the claims were presented on

January 21, 2004 and were entered by the Examiner. The claims listed in the Appendix therefore reflect the current status of the claims after all amendments presented during the course of prosecution have been entered.

SUMMARY OF INVENTION

The present invention teaches a detection article that includes an acquisition zone, a detection zone, and at least one microstructured major surface including a plurality of microchannels therein. Specification, at p. 4, lines 2-9. The microchannels are adapted to draw a fluid sample into the acquisition zone and to provide fluid flow of the fluid sample from the acquisition zone to the detection zone along the microchannels by spontaneous fluid transport. *Id.*, lines 22-27; Abstract. The detection zone also includes at least one detection element for detecting a characteristic of the fluid sample within at least one microchannel of the detection zone. *Id.* at p. 5, lines 3-5. The detection article may be formed from a plurality of film layers that are stacked to form a three dimensional article. *Id.*, lines 1-3.

ISSUES

All of the presently pending claims stand rejected by the Examiner under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. It is the Examiner's position that subject matter claimed in now pending claim 1 is new matter because it was not described in the Specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims 1-3, 5-7, 13, 39-41, 43-46, 53, 54, 60, 61, 72-75, 81, and 83-85 stand rejected by the Examiner as anticipated under 35 U.S.C. § 102 (e)(2) over Alajoki.

Claims 1-7, 39-41, 43-46, 49, 50, 53, 54, 60, 61, 72-75, 81, and 83-85 stand rejected by the Examiner as anticipated under 35 U.S.C. § 102 (e)(2) over Christian.

In view of these rejections, the issues on appeal are:

A. Whether independent claim 1 claims subject matter not described in the Specification as filed;

B. Whether Alajoki teaches or suggests spontaneous fluid transport caused by microchannels; and

C. Whether Christian teaches or suggests spontaneous fluid transport caused by microchannels.

GROUPING OF CLAIMS

Applicants contend that the appealed claims, only for the purposes of this Appeal, fall into the following groups:

For the rejection of the claims as containing new matter, all of the claims stand or fall as a group.

For the rejection over Alajoki, claims 1-3, 13, 5-7, 39-41, 43-46, 53, 54, 60, 61, 72-75, 81, and 83-85 stand or fall as one group.

For the rejection over Christian, claims 1-7, 39-41, 43-46, 49, 50, 53, 54, 60, 61, 72-75, 81, and 83-85 stand or fall as one group.

The patentability of each of the dependent claims depends on the patentability of independent claim 1. Therefore, only independent claim 1 will be directly addressed in the arguments presented below.

ARGUMENT

The Examiner has rejected all of the pending claims under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement and as being anticipated under 35 U.S.C. § 102 (e)(2).

It is the Examiner's position that the Specification does not teach and disclose the feature in claim 1 of "spontaneous fluid transport." The Examiner argues that the Specification only teaches and discloses "spontaneous and uniform fluid transport." Further, the Examiner has rejected the limitation to "fluid flow of the fluid sample from the acquisition zone to the detection zone along the microchannels by spontaneous fluid transport" as containing new matter. Specifically, the Examiner stated that "claim 1 as originally filed lacks any description of spontaneous fluid transport between the acquisition and detection zones and therefore fails to provide written support for the presently pending claim 1." Advisory Action, December 7, 2004, at p. 2.

Further, the Examiner has rejected all of the claims as being anticipated by either Alajoki or Christian. The Examiner believes that these references teach "spontaneous fluid transport" as claimed by claim 1.

I. Pending Claim 1 Does Not Contain Any New Matter

The subject matter of claim 1 was properly conveyed to one of skill in the relevant art, at the time the application was filed, to show that the inventors had possession of the claimed invention. Claim 1 properly includes limitations to providing "fluid flow of the fluid sample from the acquisition zone to the detection zone along the microchannel" and "spontaneous fluid transport." The outstanding rejections under 35 U.S.C. § 112, first paragraph, must therefore be reversed.

To satisfy the written description requirement, the patent application as originally filed must clearly allow persons of skill in the art to recognize that the Applicants invented the claimed subject matter. *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479 (Fed. Cir. 1998).

A. The Limitation To "Spontaneous Fluid Transport" Was Disclosed In The Original Application

1. "Spontaneous fluid transport" was part of the claims as filed

The limitation to "spontaneous fluid transport" was part of the claims as originally filed on July 7, 2000. Original claim 1 stated that "the plurality of microchannels draw the fluid sample into the plurality of microchannels through openings in the microchannels at least by spontaneous fluid transport." The limitation to "spontaneous fluid transport" cannot therefore be new matter as it was present in the claims as originally filed. The rejection under 35 U.S.C. § 112, first paragraph, must therefore be reversed.[1]

[1] The Examiner initially rejected the limitation to "spontaneous fluid transport" under 35 U.S.C. § 112, second paragraph, as indefinite, stating that the limitation was not "instantly specifically defined." The discussion of the definition of "spontaneous," however, is addressed below in the section dealing with the anticipation rejections.

2. "Spontaneous fluid transport" was part of the Specification as filed

The limitation to "spontaneous fluid transport" was taught and disclosed in the Specification as originally filed. The rejection under 35 U.S.C. § 112, first paragraph, must therefore be reversed.

Several sections of the Specification discuss how the microchannels provide "spontaneous fluid transport." For example, the Specification states that the acquisition zone includes "two or more channels **204** that are capable of wicking a fluid sample into the article **200** by spontaneous liquid transport." Specification, at p. 26, lines 4-6. *See* also p. 10, lines 26-27 (the film includes a "microreplicated pattern [microchannels] capable of spontaneously wicking or transporting a fluid"); p. 18, lines 18-19 ("Two general factors that influence the ability of fluid control films to spontaneously transport liquids are . . . "); and Abstract ("The film layer including an acquisition zone wherein portions of the plurality of microchannels draw the fluid sample into the plurality of microchannels through openings in the microchannels at least by spontaneous fluid transport.") The limitation to "spontaneous fluid transport" is therefore properly disclosed and taught in the Specification as originally filed.

It is conceded that certain embodiments discussed in the Specification do relate to "uniform fluid transport." For example, page 18, lines 15-16, state that "[c]ertain of the fluid control films usable with the present invention are capable of spontaneously and uniformly transporting liquids." The Applicants have chosen, however, to claim the invention wherein the microchannels provide "spontaneous fluid transport." The Examiner's position that the claim 1 limitation to "spontaneous fluid transport" is only supported if it reads "spontaneous and uniform fluid transport" improperly limits the claims to selected examples from the Specification.

Since the limitation to "spontaneous fluid transport" is supported in the Specification as filed, the limitation cannot be new matter. It is therefore respectfully requested that the rejection be reversed.

B. The Limitation To "Acquisition Zone To Detection Zone" Fluid Transport Was Disclosed In The Application As Filed

Claim 1 was amended during prosecution to recite that the microchannels are adapted "to provide fluid flow of the fluid sample from the acquisition zone to the detection zone along the microchannels by spontaneous fluid transport." The Examiner rejected this limitation as new

matter and argued that "nothing is disclosed . . . regarding acquisition zone to detection zone transport." Office Action, April 7, 2004, at p. 2. However, fluid transport from the acquisition zone to the detection zone is repeatedly discussed, taught, and disclosed in the Specification as filed. The rejection under 35 U.S.C. § 112, first paragraph, must therefore be reversed.

The Specification states that "[t]he channels **204** provide a means to wick or transport a liquid sample into the acquisition zone **210**, between the acquisition zone **210** and the detection zone **220**, and into the detection zone **220**, by spontaneous and uniform fluid transport, or capillary action, throughout the length of the channels **204**." Specification, at p. 24, lines 17-21. Moreover, other sections of the Specification discuss fluid transport from the acquisition zone to the detection zone without utilizing the term "uniform." For example, the Specification states "Referring now to **Fig. 11**, a detection article **400** of the present invention is illustrate[d] that includes a fluid control film layer **402** including adjacent coextensive channels **404** that permit the transport of a fluid from an acquisition zone **410** to a detection zone **420**." *Id.*, at p. 40, lines 9-11. Moreover, the Specification states that the channels

> are exposed on the top surface **284** through an aperture **285** formed within the cap layer **283**, which in turn forms an acquisition zone **286**. The fluid sample may be introduced at the aperture **285** and allowed to wick into the plurality of channels **282** and thus flow through the article **280** into a detection zone **287**, also provided at the opposite end of the article **280**.

Id., at p. 27, lines 5-9. Moreover, "[t]he channels **204** are continuous from the acquisition zone **210** through the detection zone **220** providing continuity of sample flow throughout the detection article **200**." *Id.*, at p. 28, lines 5-7. "In preferred embodiments, sample flow within the channels **204** is also discrete, in that the liquid sample enters each individual channel and the sample within a specific channel remains in that channel from the acquisition zone **210** through the detection zone **220**." *Id.*, lines 11-14.

The Specification teaches and discloses fluid transport from the acquisition zone to the detection zone along the microchannels. As previously shown, the Specification also teaches and discloses that the fluid transport is spontaneous. Therefore the application as filed clearly teaches and discloses acquisition to detection zone spontaneous fluid transport. It is therefore respectfully requested that this rejection be reversed.

II. The Pending Claims Are Not Anticipated By The Cited References

It is well established that for a reference to anticipate a claim under § 102, every claim limitation must be expressly or inherently taught by the reference. Alajoki and Christian do not anticipate the claims of the present application because neither reference reports a detection article with microchannels that provide "spontaneous fluid transport." Contrary to the Examiner's arguments, both Alajoki and Christian teach detection devices and cards wherein the fluid transport is not "spontaneous" as presently claimed. In Alajoki and Christian the fluid transport is controlled by an external structure, such as a wick or roller. The rejection of the claims as anticipated under these two references must therefore be reversed.

The Examiner has treated the detection apparatuses of Alajoki and Christian as black boxes, i.e., anything added to the inside of the hypothetical box for urging fluid transport, whether it is an absorbent or a roller, still results in "spontaneous fluid transport." In other words, the Examiner feels that when you can detect fluid transport from outside the imaginary box, anything inside the imaginary box that aids in the fluid transport still results in the transport being spontaneous. The Specification as filed, however, only considered "spontaneous fluid transport" as being caused by the microchannel. Any additional structure that is not part of the microchannel surface is therefore "external" for purposes of causing spontaneous fluid transport.

The rejection under both of Alajoki and Christian are based, at the core, on the Examiner's interpretation of the term "spontaneous." The meaning of this term will therefore first be addressed.

A. "Spontaneous" Means Fluid Transport Without Structure "External To The Microchannel"

The microchannels are the only structures in the claimed invention capable of wicking the fluid sample by spontaneous transport into the acquisition zone and then to the detection zone. Any article, absorbent, wick, pressure device, or other structure that causes or urges liquid transport in addition to the channel formed by the film surface therefore does not provide "spontaneous fluid transport" as claimed.

To understand the Examiner's contrary interpretation, it may be helpful to review the history of the Examiner's objections to the term "spontaneous."

In the third Office Action the Examiner rejected the "spontaneous fluid transport" limitation in claim 1 under 35 U.S.C. § 112, second paragraph, stating the term was not

"instantly specifically defined." Office Action, August 18, 2003, at p. 4. Proposing a definition, the Examiner cited one possible interpretation of "spontaneous" as "occurring without apparent external cause." *Id.* The Examiner then stated that the term "external" had also not been defined in the Specification and then postulated two possible interpretations. One interpretation of "external" put forth by the Examiner was 'external to the sample.' *Id.* at p. 5. Another interpretation of "external" put forth by the Examiner was 'external to the detection article.' *Id.* Neither interpretation is correct. The Specification and claims clearly utilize the term "spontaneous" to mean fluid transport without any aid from structure 'external to the microchannels.'

The plain language of the claims recites that "spontaneous" refers to a property of the microchannels. Claim 1 states that "the microchannels are adapted to draw a fluid . . . and to provide fluid flow . . . by spontaneous fluid transport." The plain language of the claims therefore recites that the spontaneous fluid transport is carried out solely by the microchannel without any aid from other structures. In addition, the Specification supports this interpretation of the plain language of the claims.

The Specification states that "[t]he acquisition zone preferably includes two or more channels that are capable of wicking a fluid sample into the article by spontaneous liquid transport." Specification, at p. 4, lines 23-25. Moreover, "the acquisition zone **210** preferably includes two or more channels **204** that are capable of wicking a fluid sample into the article **200** by spontaneous liquid transport." *Id.* at p. 26, lines 4-6. "Fluid Transport Film ("FTF") refers to a film or sheet or layer having at least one major surface comprising a microreplicated pattern capable of spontaneously wicking or transporting a fluid." Specification, at p. 10, lines 25-27. "The channels **204** are continuous from the acquisition zone **210** through the detection zone **220** providing continuity of sample flow throughout the detection article **200**." *Id.* at p. 28, lines 5-7. Furthermore, "channels **204** provide a means to wick or transport a liquid sample into the acquisition zone **210**, between the acquisition zone **210** and the detection zone **220**, and into the detection zone **220**, by spontaneous and uniform fluid transport, or capillary action, throughout the length of the channels **204**." Specification, at p. 24, lines 17-21.

Finally, the Specification distinguishes alternative embodiments that utilize aid from structure 'external to the microchannel' to urge fluid transport. "[I]t is to be understood that other fluid transport methods may additionally be provided, such as pressure differential,

electrophoresis or pumping, if desired." Specification, at p. 26, lines 14-16. Moreover, "[t]he channels of fluid control films usable with the invention preferably provide more effective liquid flow than is achieved with webs, foam, or tows formed from fibers." Specification, at p. 11, lines 19-20.

The Specification clearly utilizes the term spontaneous to mean fluid transport without the aid of any structure 'external to the microchannels' through which the fluid is transported.

B. Claim 1 Is Not Anticipated By Alajoki

1. Alajoki does not teach the claimed spontaneous fluid transport

Alajoki does not teach or suggest a microfluidic device including polymeric film layers having a plurality of microchannels formed therein that provide "spontaneous fluid transport." Rather, Alajoki reports a channel system that incorporates an absorbent wick material that absorbs fluid and promotes the fluid transport. Alajoki, Col. 4, lines 43-44. The Examiner stated that the absorbent material in Alajoki is "internal to the device after its placement therein and thus is not an external agency, external influence, force, cause, or treatment." Advisory Action, December 7, 2004, at p. 3. The absorbent material, however, is additional structure that aids fluid transport and is 'external to the microchannels.'

Alajoki reports "methods for achieving continuous and consistent flow in a microfluidic device by modulation of pressure downstream from any fluid flow that requires regulation." Col. 6, lines 23-25. An absorbent wick material may modulate the fluid flow.[2] *Id.*, col. 6, lines 29-32. Types of wicks include porous materials or cellulosic materials. *Id.*, col. 9, line 55 – col. 11, line 36. "The wick need only be placed at a location that allows it to take up fluid and pull the material or sample stream toward it." *Id.*, col. 10, lines 57-59. As reported in Alajoki, the absorbent wick may be placed entirely in a fluid well, so that it is partially in and out of the fluid well, or partially in a fluid well and partially in a channel. In any case, the wick is at least partially external to the channel. Moreover, the absorbent wick is not part of the thin film that is the structure forming the channel. From a perspective 'external to the microchannel,' the fluid transport is not spontaneous in Alajoki because the fluid transport is not caused by the microchannels without the aid of any other structure.

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[2] Alternatively, Alajoki reports that the fluid flow may be modulated by "electrokinetic or pressure based injection or withdrawal downstream of the channel region containing the sample stream to be modulated." Alajoki, col. 6, lines 34-37. For purposes of the outstanding rejection, however, only the absorbent wick is discussed as this embodiment was the focus of the Examiner's rejections.

In contrast, claim 1 provides for microchannels which themselves cause "spontaneous fluid transport." The microchannels "provide fluid flow of the fluid sample from the acquisition zone to the detection zone along the microchannels by spontaneous fluid transport." Claim 1. Any structure that causes fluid transport other than the actual microchannels formed by the thin film is therefore external to the structure of the microchannels and results in fluid transport that is not spontaneous. Moreover, the Specification distinguishes using absorbent wicks like those reported in Alajoki: "The channels of fluid control films usable with the invention preferably provide more effective liquid flow than is achieved with webs, foam, or tows formed from fibers." Specification, at p. 11, lines 19-21.

The Examiner further argues that "absorbent material is reasonably interpreted" as a factor "influencing spontaneous fluid transport." Office Action, June 8, 2004, at p. 4. It is not disputed that the addition of an absorbent wick to a system will effect fluid transport. However, the addition of an absorbent wick does not change the topography of a film surface to create microchannels having "spontaneous fluid transport" as instantly claimed. *Id.* The modifications of the topography discussed in the Specification involve changing the nature of the film itself by chemical modification of the surface or deposition of extremely thin layers of materials on the surface. *See* Specification, at p. 20, line 17. Examples include modifying the film by incorporating a surfactant or attaching a silane. The Specification distinguishes those devices that incorporate fibers:

> The walls of channels formed in fibers will exhibit relatively random undulations and complex surfaces that interfere with flow of liquid through the channels. In contrast, the channels in the present invention are precisely replicated, with high fidelity, from a predetermined pattern and form a series of individual open capillary channels that extend along a major surface.

Specification, at p. 11, lines 21-25. While any material placed in the channel may influence the fluid transport, the absorbent wick reported in Alajoki is not "reasonably interpreted as one of applicant's own factors influencing spontaneous fluid transport" for purposes of the claimed invention.

Alajoki fails to anticipate claim 1. Because Alajoki includes an absorbent wick in addition to channels, Alajoki does not achieve spontaneous fluid transport as claimed. Alajoki therefore does not anticipate the claimed invention and the anticipation rejection based thereon must be reversed.

C. Claim 1 Is Not Anticipated By Christian

The Examiner argues that in Christian "the solenoid roller is reasonably a part of the device of Christian and therefore not external to the device." Advisory Action, December 7, 2004, at p. 4. The Christian reference does not anticipate claim 1 because the roller induced fluid transport reported by Christian is clearly not spontaneous from the proper point of view. The fluid transport is caused by structure external to the microchannels, i.e., the roller. Moreover, the roller is external to the detection device. The Christian reference therefore does not anticipate claim 1, which reports microchannels adapted "to provide fluid flow . . . by spontaneous fluid transport."

The detection device reported by Christian is an assay card having a laminate construction with recessed channels and chambers. Abstract. "The card is activated and analysis and/or treatment carried out by passing a roller bar or other pressure device *over the top of the card* to force solutions and reagents through the various card channels." Abstract (emphasis added). The card is "passed under a solenoid operated roller 130 which squeezes the test sample out of channel 122 through opening 126." In addition, "[t]he cover layer 134 for card 121 (see FIG. 13) is preferably made from a suitably flexible material which can be deformed by roller 130 so that the various solutions in channels 122-125 can be moved by the peristaltic action induced by roller 130." Christian, col. 12, lines 61-65. "Preferably the roller bar or pressure bar 80' will be housed within a cassette or other housing device 82' which has an opening 84' into which the microassay card 10' can be fed in the direction shown by arrow 86'." *Id.*, col. 15, lines 42-45. The roller bar of Christian is an external structure to the channels through which the fluid in Christian flows and is furthermore external to the assay card that contains the channels. The fluid transport in Christian is therefore not spontaneous as claimed in the present invention because fluid transport is caused or aided by structure other than or external to the reported channels.

In contrast, the present invention claims microchannels that provide spontaneous fluid transport without aid from any additional structure. Christian therefore does not anticipate the claimed invention and the rejection based thereon must be reversed.

CONCLUSION

The Specification teaches a detection article wherein the microchannels "provide fluid flow of the fluid sample from the acquisition zone to the detection zone along the microchannels by spontaneous fluid transport." The references cited by the Examiner, however, fail to teach or suggest this recited feature of the claimed invention. Accordingly, pending claims 1-9, 13, 39-41, 43-46, 49, 50, 53, 54, 60, 61, 72-75, 77 and 81-85 are in condition for allowance. Applicants respectfully requests that the Board reverse the outstanding rejections of the pending claims, and that the application be returned to the Examiner for processing in accordance with that reversal.

The appropriate fee of $500 for the filing and consideration of this Appeal Brief is enclosed. Should any additional fee be required, the Commissioner is authorized to charge our Deposit Account No. 06-0029 and is requested to notify us of the same.

Respectfully Submitted,

RAYMOND P. JOHNSTON ET AL.

Date: February 2, 2005

By: 

Paul W. Busse, 32,403
FAEGRE & BENSON LLP
2200 Wells Fargo Center
90 South Seventh Street
Minneapolis, MN 55402-3901
Telephone: 612-766-8073

M2:20681594.04

APPENDIX

Pending Claims

1. (Previously Amended) A detection article comprising:

at least one polymeric fluid control film layer including an acquisition zone, a detection zone and at least one microstructured major surface including a plurality of microchannels therein, wherein the microchannels are adapted to draw a fluid sample into the acquisition zone through openings in the microchannels, and to provide fluid flow of the fluid sample from the acquisition zone to the detection zone along the microchannels by spontaneous fluid transport, the detection zone including at least one detection element that facilitates detection of a characteristic of the fluid sample within at least one microchannel of the detection zone.

2. (Original) The detection article of claim 1, wherein at least one microchannel is comprised of sidewalls that are configured to define the microchannel, and the sidewalls extend continuously from the opening of that microchannel and through the acquisition and detection zones of the detection article with the detection element supported within a continuous microchannel.

3. (Original) The detection article of claim 2, further comprising a plurality of microchannels that are each comprised of sidewalls that extend from the opening in that microchannel through the acquisition and detection zones to define a plurality of continuous microchannels that provide discrete fluid transfer paths from one another.

4. (Original) The detection article of claim 3, wherein one of the plurality of continuous microchannels supports a different detection element from a detection element that is supported within another of the plurality of continuous microchannels.

5. (Original) The detection article of claim 1, further comprising an intermediate zone extending between the acquisition zone and the detection zone.

6. (Original) The detection article of claim 1, wherein at least a portion of the film layer is hydrophilic.

7. (Original) The detection article of claim 6, wherein the hydrophilic portion of the film layer comprises a hydrophilic material.

8. (Original) The detection article of claim 7, wherein the hydrophilic material is poly(vinyl alcohol).

9. (Original) The detection article of claim 7, wherein the hydrophilic material comprises a less hydrophilic material combined with an additive to increase hydrophilicity.

10.-12. (Cancelled)

13. (Original) The detection article of claim 1, wherein the microstructured surface is configured to modify a surface energy of the surface to improve spontaneous fluid transport into and along the microchannels.

14.-38. (Cancelled)

39. (Original) The detection article of claim 1, wherein the at least one detection element is associated with at least one microchannel of the film layer.

40. (Original) The detection article of claim 39, wherein the at least one detection element is positioned within one of the plurality of microchannels.

41. (Original) The detection article of claim 39, wherein the at least one detection element is positioned adjacent one of the plurality of microchannels.

42. (Cancelled)

43. (Original) The detection article of claim 1, wherein the detection zone comprises a plurality of detection elements.

44. (Previously Amended) The detection article of claim 43, wherein at least one of the plurality of detection elements is associated with each microchannel of the film layer.

45. (Original) The detection article of claim 44, wherein at least one of the plurality of detection elements is positioned within one of the plurality of microchannels.

46. (Original) The detection article of claim 44, wherein at least one of the plurality of detection elements is positioned adjacent one of the plurality of microchannels.

47.-48. (Cancelled)

49. (Original) The detection article of claim 43, wherein at least one of the plurality of detection elements is different than at least one other of the detection elements.

50. (Original) The detection article of claim 49, wherein each detection element is different than all other detection elements.

51.-52. (Cancelled)

53. (Original) The detection article of claim 43, wherein at least one of the plurality of detection elements comprises an assay reagent.

54. (Original) The detection article of claim 53, wherein the assay reagent is chosen from the group consisting of fluorogenic indicators, chromogenic indicators, electrochemical reagents, agglutination reagents, analyte specific binding agents, amplification agents, enzymes, catalysts,

photochromic agents, dielectric compositions, analyte specific reporters, enzyme-linked antibody probes, DNA probes, RNA probes, fluorescent beads, and phosphorescent beads.

55.-59. (Cancelled)

60. (Original) The detection article of claim 1, wherein the at least one detection element comprises an assay reagent.

61. (Original) The detection article of claim 60, wherein the assay reagent is chosen from the group consisting of fluorogenic indicators, chromogenic indicators, electrochemical reagents, agglutination reagents, analyte specific binding agents, amplification agents, enzymes, catalysts, photochromic agents, dielectric compositions, analyte specific reporters, enzyme-linked antibody probes, DNA probes, RNA probes, fluorescent beads, and phosphorescent beads.

62.-71. (Cancelled)

72. (Original) The detection article of claim 1, wherein the openings in the microchannels are provided at one end of the plurality of microchannels.

73. (Original) The detection article of claim 72, wherein the microchannels are configured so as to position the openings of the microchannels across a width of the detection article.

74. (Original) The detection article of claim 72, wherein the microchannels are configured so as to position the openings of the microchannels along at least a portion of the length of the detection article.

75. (Original) The detection article of claim 1, wherein the openings in the microchannels are provided at a top surface of the microchannels.

76. (Cancelled)

77. (Original) The detection article of claim 1, wherein the detection zone at least partially overlaps the acquisition zone.

78.-80. (Cancelled)

81. (Original) The detection article of claim 1, wherein the microchannels are defined by sidewalls and a bottom wall between them.

82. (Original) The detection article of claim 1, wherein the microchannels are defined by sidewalls that converge together at a bottom of the microchannel.

83. (Original) The detection article of claim 1, wherein the microchannels extend continuously over the film layer.

84. (Original) The detection article of claim 1, wherein the microchannels extend from one side edge of the film layer to another side edge of the film layer.

85. (Original) The detection article of claim 1, wherein the characteristic of the fluid sample to be detected is chosen from the group consisting of color change, fluorescence, luminescence, turbidity, electrical conductivity, voltage change, light absorption, light transmission, pH, and change in physical phase.

86.-101. (Cancelled)